

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

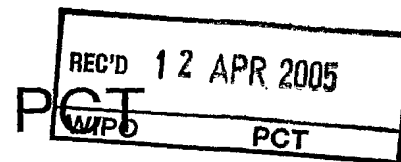
Applicant's or agent's file reference 525914600WO1	FOR FURTHER ACTION	See item 4 below
International application No. PCT/US2004/023721	International filing date (<i>day/month/year</i>) 22 July 2004 (22.07.2004)	Priority date (<i>day/month/year</i>) 01 August 2003 (01.08.2003)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant ABBOTT LABORATORIES		

1.	This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 <i>bis</i> .1(a).																								
2.	This REPORT consists of a total of 12 sheets, including this cover sheet. In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.																								
3.	<p>This report contains indications relating to the following items:</p> <table style="width: 100%;"> <tr> <td style="width: 10%; text-align: center;"><input checked="" type="checkbox"/></td> <td style="width: 30%;">Box No. I</td> <td style="width: 60%;">Basis of the report</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>	<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input checked="" type="checkbox"/>	Box No. II	Priority	<input checked="" type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input checked="" type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement																							
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<input type="checkbox"/>	Box No. VIII	Certain observations on the international application																							
4.	The International Bureau will communicate this report to designated Offices in accordance with Rules 44 <i>bis</i> .3(c) and 93 <i>bis</i> .1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44 <i>bis</i> .2).																								

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Date of issuance of this report 06 February 2006 (06.02.2006) Authorized officer <div style="text-align: center; font-size: 1.2em;">Simin Baharlou</div>
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PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY



To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2004/023721

International filing date (day/month/year)
22.07.2004

Priority date (day/month/year)
01.08.2003

International Patent Classification (IPC) or both national classification and IPC
A61F2/44, A61F2/46

Applicant
ABBOTT LABORATORIES

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office - Gitschiner Str. 103
D-10958 Berlin
Tel. +49 30 25901 - 0
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Authorized Officer

Stach, R

Telephone No. +49 30 25901-551



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2004/023721

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2004/023721

Box No. II Priority

1. ☒ The following document has not been furnished:

- ☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).
- ☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. ☐ The International Searching Authority has not been able to consider the validity of the priority claim because a copy of the earlier application whose priority has been claimed was not available to the International Searching Authority at the time that the search was conducted (Rule 17.1). This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.
4. Additional observations, if necessary:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2004/023721

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 74, 88-95, 6-15, 31, 32, 36-73, 75-87

because:

- ☒ the said international application, or the said claims Nos. 74, 88-95 relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the whole application or for said claims Nos. 74, 88-95, 6-15, 31, 32, 36-73, 75-87

- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

- ☐ has not been furnished

- ☐ does not comply with the standard

the computer readable form

- ☐ has not been furnished

- ☐ does not comply with the standard

- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- ☐ See separate sheet for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2004/023721

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:
- ☐ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☒ not paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. 1-5, 16-30, 33-35

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	16, 17, 20
	No: Claims	1-5, 18, 19, 21-30, 33-35
Inventive step (IS)	Yes: Claims	
	No: Claims	16, 17, 20
Industrial applicability (IA)	Yes: Claims	1-5, 16-30, 33-35
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item III.

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

Re Item IV.

The separate inventions/groups of inventions are:

Claims 1-5, 16-30, 34, 35

A spinal implant, comprising:

- a top, wherein at least a portion of the top is configured to contact a first vertebra;
- a bottom, wherein at least a portion of the bottom is configured to contact a second vertebra;
- a curved anterior side; a curved posterior side; and
- an opening extending through the spinal implant from the top to the bottom further comprising a proximal end, wherein the proximal end is substantially flat.

Claims 6-15, 31, 32, 36-58

A spinal implant, comprising:

- a body, wherein the body comprises:
 - a top comprising radially positioned protrusions, wherein the top protrusions are configured to contact a first vertebra;
 - a bottom comprising radially positioned protrusions, wherein the bottom protrusions are configured to contact a second vertebra;
 - a curved anterior side; a curved posterior side; and
 - an opening extending through the body from the top to the bottom.

Claims 59-73

A rasp, comprising:

- an outer shaft;
- an inner shaft extending through the outer shaft;
- an end member pivotally coupled to the distal end of the inner shaft; and
- wherein a distal end of the outer shaft is configured to engage a proximal end of the

end member.

Claims 75-85

An implant inserter, comprising:

an outer shaft;

an inner shaft extending through the outer shaft;

arms coupled to a distal end of the inner shaft; and

wherein the outer shaft is configured to engage the arms.

Claims 86, 87

An instrumentation kit, comprising:

a cutting edge distractor;

a rasp with a pivot able end member;

an implant inserter; and

one or more guides.

The present application lacks unity within the meaning of Rule 13.2 of the PCT for the following reasons:

The document US6143032 cited in the present search report discloses (the references in parenthesis applying to this document) (see the figure 1 and claim 1):

A spinal implant (1), comprising:

a top, wherein at least a portion of the top is configured to contact a first vertebra;

a bottom, wherein at least a portion of the bottom is configured to contact a second vertebra;

a curved anterior side (4); a curved posterior side (5); and

an opening extending through the spinal implant from the top to the bottom.

Over this prior art the potential special technical features (in the meaning of PCT Rule 13.2) claimed in the application are:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

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Group 1 (claims 1):

a proximal end, which is substantially flat;

(problem: facilitating to manoeuvre the implant after disconnection from the initial implant inserter)

Group 2 (claim 36) :

a top comprising radially positioned protrusions, wherein the top protrusions are configured to contact a first vertebra;

a bottom comprising radially positioned protrusions, wherein the bottom protrusions are configured to contact a second vertebra;

(problem: fixation of the implant in the intervertebral space)

Group 3 (claim 59):

a rasp, comprising:

an outer shaft;

an inner shaft extending through the outer shaft;

an end member pivotally coupled to the distal end of the inner shaft; and

wherein a distal end of the outer shaft is configured to engage a proximal end of the end member;

(problem: facilitating the handling of a rasp)

Group 4 (claim 75):

an implant inserter, comprising:

an outer shaft;

an inner shaft extending through the outer shaft;

arms coupled to a distal end of the inner shaft; and

wherein the outer shaft is configured to engage the arms;

(problem: facilitating the implantation of an implant)

Group 5 (claim 86):

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2004/023721

an instrumentation kit, comprising:
a cutting edge distractor;
a rasp with a pivot able end member;
an implant inserter; and
one or more guides;

(problem: providing a complete set of instruments for a surgical implantation procedure).

US 6517544 (see figures 16 - 18 and column 12, line 66 - column 13, line 46) cited in the search report discloses a "a rasp with a pivotable end member and an outer shaft". The only common technical feature of claims 59 (group 3) and 86 (group 5) is therefore already known in state of the art.

No same or corresponding potential special technical feature can be found between the above mentioned subjects. There is therefore no technical relationship involving same or corresponding potential special technical features between any two of these subjects. The inventions defined in the above mentioned subjects are thus not considered linked by a single general inventive concept (Rule 13.1 PCT).

The application relates to a plurality of inventions, or groups of inventions, in the sense of Rule 13.1 PCT. They have been divided as defined above. If the applicant pays additional fees for one (or more) not yet searched group(s) of invention(s), then the further search(es) may reveal further prior art that gives evidence of a further lack of unity 'a posteriori' within one (or more) of the not yet searched group(s). In such a case only the first invention in this (each of these) group(s) of inventions, which is considered to lack unity of invention, will be the subject of a search. No further invitation to pay further additional fees will be issued. This is because Article 17(3)(a) PCT stipulates that the ISA shall establish the International Search Report on those parts of the international application which relate to the invention first mentioned in the claims ('main invention') and for those parts which relate to inventions in respect of which the additional fees were paid. Neither the PCT nor the PCT guidelines provide a legal basis for further invitations to pay further additional search fees (W17/00, point 11 and W1/97, points 11-16).

Re Item V.

1 The following documents are referred to in this communication:

D1 : US 2003/100950 A1 (MORET OLIVIER) 29 May 2003 (2003-05-29)

D2 : WO 98/56319 A (SDGI HOLDINGS INC ; MCKAY WILLIAM F (US)) 17
December 1998 (1998-12-17)

D3 : US 6 143 032 A (SCHAFER BERND ET AL) 7 November 2000 (2000-11-07)

D4 : WO 02/17823 A (KIM BYUNG SOO ; KIM JUNG SUNG (KR); KIM YOUNG
SOO (KR); HAN JUNG SOO () 7 March 2002 (2002-03-07)

2 INDEPENDENT CLAIM 1

2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

Document D1 discloses (the references in parenthesis applying to this document)
(see the figure 1 and claim 1):

A spinal implant (1), comprising:

a top, wherein at least a portion of the top is configured to contact a first vertebra;

a bottom, wherein at least a portion of the bottom is configured to contact a second vertebra;

a curved anterior side (4); a curved posterior side (5); and

an opening extending through the spinal implant from the top to the bottom.

2.2 Furthermore all the technical features of claim 1 are disclosed in each of the documents D2, D3 and D4.

3 DEPENDENT CLAIMS 2-5, 16-30, 34, 35

Dependent claims 2-5, 16-30, 34, 35 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT).

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2004/023721